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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/905,046 08/01/97 CASSELS

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HM12/0621

JOHN F MORAN
OFFICE OF COMMAND JUDGE ADVOCATE
HQ USAMRDC
DEPARTMENT OF THE ARMY FORT DETRICK
FREDERICK MD 21702-5012

EXAMINER

DEVI, S

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 06/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/905,046

Applicant(s)
Cassels et al.

Examiner
S. Devi, Ph.D.

Group Art Unit
1641



☒ Responsive to communication(s) filed on 05/18/2000.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-11 ~~is~~/are pending in the application.

Of the above, claim(s) 7, 10, and 11 ~~is~~/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-6, 8, and 9 ~~is~~/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Petition Granted

1) Acknowledgment is made of Applicants' petition filed 05/18/2000 (paper no. 5) to revive the instant application under 37 CFR 1.137(b) that was previously abandoned on 12/22/98 (paper no. 4) due to the Applicants' failure to respond to a previous Office Action in a timely manner. The Office granted the petition 06/08/2000 (paper no. 7).

Preliminary Amendment

2) Acknowledgment is made of Applicants' preliminary amendment filed 06/11/1998 (paper no. 3), which amendment has been entered into the case. With this, Applicants have amended claim 1 and the specification.

Election

3) Acknowledgment is made of Applicants' election filed 05/18/2000 (paper no. 6), of invention I, claims 1-6, 8 and 9, in response to the restriction requirement mailed 06/12/1998 (paper no. 2). Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P § 818.03(a)).

Status of Claims

4) Claim 1 has been amended.

Claims 7, 10 and 11 are withdrawn from consideration as being directed to non-elected inventions. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03. These assay/method claims will be retained as pending claims pursuant to the rejoinder provisions of M.P.E.P § 821.04 and will be withdrawn from consideration until such time as the product of invention I (the elected group) is deemed allowable. The Examiner in charge of the instant application will then determine if claims of invention II include all the limitations of the allowable product claims, prior to determining if rejoinder will be permitted under M.P.E.P § 821.04. Applicants are reminded that in order for claims drawn to the method of use to be rejoined with allowable product claims, the method claims must be of the same scope as the allowable product claims.

Claims 1-11 are pending in the instant application.

Claims 1-6, 8 and 9 are under examination and an Action on the Merits for these claims is issued.

Sequence Listing

5) Acknowledgment is made of Applicants' sequence listing filed 01 August 1997, which has been entered into the case on 07/07/1998 (paper no. 8).

Specification / Informalities

6) The instant specification is objected to because:

(a) The recitation "(Seq. #1)" in line 7 of page 1 and line 21 of page 2, the recitation "(Seq. #2)" in line 9 of page 1, and the recitation "(Seq. #3)" in line 4 of page 3 are incorrect. It is suggested that Applicants replace the recitation "Seq. #" with --SEQ ID NO: --.

(b) In lines 15 and 16 of page 7, the address of the American Type Culture Collection is incorrect. Effective 23 March 1998, ATCC has a new address: 10801 University Boulevard, Manassas, VA 20110-2209. Amendment to the specification is suggested to reflect this.

(c) The use of the trademark in the instant specification has been noted. For example, see page 2, line 37 and page 3, line 21: "Macrosep"; and page 18, lines 21, 23 and 26: "Tween 20". The recitations should be capitalized wherever they appear and be accompanied by the generic terminology. Each letter of the trademark must be capitalized. See M.P.E.P 608.01(V) and Appendix I. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

(d) On page 7, line 16, the underlining used for the recitation "ATCC HB-12163" is objected to [Emphasis in original]. It is suggested that Applicants remove the underlining, since it serves no purpose.

Rejection(s) under 35 U.S.C § 112, First Paragraph

7) Claims 1-6, 8 and 9 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not fully comply with 37 C.F.R § 1.801-1.809. There is insufficient evidence that the claimed biological material is (a) known and readily available to the

public; (b) reproducible from the written description, e.g. sequenced; or (c) deposited.

Instant claims are directed to a monoclonal antibody produced by hybridoma 96-109FE8 IH11 and a composition comprising the same. It is apparent that the recited hybridoma is required to practice the claimed invention. As a required element, the recited hybridoma must be known and be readily available to the public, or obtainable by a reproducible method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the hybridoma. The instant specification on page 7, lines 14-16, states that the hybridoma identified as 96-109FE8 IH11 has been deposited at the American Type Culture Collection and has been given the designation ATCC HB-12163. If the deposit is made under the provisions of the Budapest Treaty, then an affidavit or declaration by Applicants or assignees, or a statement by an attorney of record over his or her signature, who has authority and control over the conditions of the deposit, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each state. Absent further guidance or evidence, one skilled in the art cannot practice the claimed invention without undue experimentation. Applicants' attention is directed to *In re Lundack*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 C.F.R § 1.801-1.809 for further information concerning deposit requirement. Additionally, there is no evidence showing that the 96-109FE8 IH11 is the same as the one deposited as ATCC HB-12163. Applicants are encouraged to submit a copy of the contract with the depository to document this. Applicants are also requested to amend the specification to include complete deposit information for the hybridoma ATCC HB-12163 including full and correct address of the depository and the date of deposition.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

8) Claims 1-6, 8 and 9 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1 is vague in the recitation "sequence SAVALTYS" without reciting that it is an amino acid sequence (see last line). It is suggested that Applicants change the recitation to --amino acid sequence SAVALTYS-- to obviate the rejection.

(b) Claim 2 lacks proper antecedence for the recitation "A monoclonal antibody of claim 1" (see line 1). It is suggested that Applicants change the recitation to --The monoclonal antibody of claim 1-- to obviate the rejection.

(c) Claims 3 and 8 lack proper antecedence for the recitation "a monoclonal antibody of claim 1". It is suggested that Applicants change the recitation to --The monoclonal antibody of claim 1-- to obviate the rejection.

(d) Claim 4 lacks antecedent basis for the recitation "the" antibody/-CS4-CFA/I family protein complex".

(e) Claims 1 and 4 are confusing in the use of the abbreviation "CS4-CFA/I" in the claim language. It is suggested that these abbreviations be recited as full terminologies at first occurrence in the claims, with their abbreviated recitations retained in parentheses.

(f) Claim 4 lacks proper antecedence for the recitation "A composition of claim 3" (see line 1). It is suggested that Applicants change the recitation to --The composition of claim 3-- to obviate the rejection.

(g) Claim 5 lacks proper antecedence for the recitation "a composition of claim 4". It is suggested that Applicants change the recitation to --The composition of claim 4-- to obviate the rejection.

(h) Claims 2-6, 8 and 9 stand rejected under 35 U.S.C. § 112, second paragraph, because of the defect(s) in the base claim(s) identified above in subparagraphs (a) through (g).

Objections

9) Claims 1-4 are objected to for the following reasons:

(a) Claim 1 is incorrect in the recitation of "(Seq. #2)" (see line 4 of the claim). The objection can be obviated by changing the recitation to --(SEQ ID NO. 2)--.

(b) For clarity, it is suggested that Applicants change the recitation "which" in line 3 of claim 1 to --and--.

(c) In claim 3, it is suggested that Applicants delete the recitation "of matter" (see line

1), since the recitation is unnecessary.

(d) In order to distinctly claim the subject matter, in claims 1 and 2, it is suggested that Applicants delete the laboratory designation "96-109FE8 IH11" for the recited hybridoma and replace it with the depository accession number --ATCC HB-12163--.

(e) Claim 1 is grammatically incorrect in the recitation "CS4-CFA/I family proteins". It is suggested that Applicants change the recitation to --CS4-CFA/I family of proteins-- to obviate the objection.

(f) In claim 4, it is suggested that Applicants delete the recitation "family" (see line 3), since the recitation is unnecessary and/or non-idiomatic.

Remarks

10) Claims 1-6, 8 and 9 stand rejected. These claims are free of prior art currently of record.

11) The prior art made of record and not relied upon is considered pertinent to Applicants' disclosure:

- Cassels *et al.* (WO 96/38171) teach raising antibodies against the proteins of all members of the *E. coli* family CS4-CFA/1 using as immunogen a consensus peptide of 36 amino acids (see abstract).

- Cassels (US 5,914,114) discloses polyclonal antibodies raised to and reactive with a consensus peptide of *E. coli* CS4-CFA/1 family of proteins (see Examples 1 and 7). The antibodies are appropriate for application in agglutination of whole bacteria (see Example 7).

12) Papers related to this application may be submitted to Group 1600, AU 1641 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242.

13) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. The Examiner can normally be reached on Monday to Friday from 8.00 a.m to 4.00 p.m. A message may be left on the Examiner's voice mail system.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

\$D
S. Devi
Patent Examiner
June 2000